REMARKS/ARGUMENTS

Claims 1-20 are pending in the above-referenced application. No amendment has been made by the present Request for Reconsideration.

This is a Response to the Final Office Action dated November 14, 2007 wherein the Examiner rejected claims 1-20 under §103(a) as being unpatentable over Woehr et al (USPN 6,117,108) in view of Rogers et al. (USPN 5,405,323). Applicant is not certain whether the claims are also rejected by the combination of the '278 Woehr reference in view of the '323 Rogers reference due to the mix-up in jumping from the '108 and the '278 patents in the Detailed Action section of the Final Office Action. Notwithstanding that the second combination is also applied by the Examiner, the same comments regarding the first combination will apply.

In view of the following remarks, reconsideration of the rejected claims and a notice of allowance are respectfully requested.

§103(a) Rejection by Woehr et al. ('108) in view of Rogers et al. ('323)

In rejecting claims 1, 3, 4, 5-11 the Examiner contends that Woehr ('108) discloses all the elements and limitations disclosed in claim 1, except for "a check valve disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after removal of the needle". (Pg. 3 of the Final Action). The Examiner then relied on Rogers ('323) to disclose "a check valve 10 disposed between the catheter tube 16 and the needle guard element (26 and 33) in the catheter hub (13) through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle (figures 1 and 2 and Col. 3, lines 30-55 and Col. 4, lines 23-62). The Examiner concluded that "since the function of catheters is to allow controlled delivery of medicaments or removal of blood from a patient's vessel, it would have been obvious to one of ordinary skill in the art to modify Woehr's catheter insertion device with a check valve to control intravenous fluid transmission and fluid sampling by closing the fluid pathway after removing the needle".

Preliminarily, Applicant reminds the Examiner that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP 706.02(j).

Independent claim 1 recites a catheter insertion device comprising a hollow-cylindrical catheter hub having a catheter tube attached a distal end thereof, a needle hub having a hollow needle attached thereto and extending through the catheter hub and the catheter tube when in a ready position, a needle guard element arranged displaceably on the needle in the catheter hub and having an engaging section which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter hub, wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle (emphasis added)

Independent claim 10 recites a catheter insertion device comprising: a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub, said needle projecting, through the lumen of the catheter tube; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub; and a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve (emphasis added).

Independent claim 11 recites a catheter insertion device comprising: a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub,

said needle projecting, through the lumen of the catheter tube and comprising an engaging section near a needle tip; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub, said valve comprising an opening and the needle projecting through the opening; and a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub (emphasis added).

Thus all three independent claims disclose a check valve for regulating fluid flow. Furthermore, all three independent claims make clear that both the check valve and the needle guard are positioned in the catheter hub. Still furthermore, independent claim 1 recites a catheter assembly wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub. Somewhat similarly, claim 11 recites a catheter assembly in which the needle guard is positioned between the valve and the needle hub. Claim 10 recites a different aspect of a catheter assembly in which a valve for regulating fluid flow is positioned inside the interior cavity of the catheter hub, and a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve.

In contrast, the '108 Woehr patent discloses a safety IV catheter, in which the needle tip is automatically covered after the needle is withdrawn to prevent the health-care worker from making accidental contact with the needle tip. The safety IV catheter disclosed by Woehr, as shown in Figs. 10A and 10B and described in the specification at Col. 8:17 to Col. 9:8, show a needle guard 120 disposed in the interior cavity of a catheter hub 28 and having a pair of arms 122, 124 crossing the needle shaft 16 from opposite sides of the shaft. When the needle is withdrawn past the distal walls 130, the two arms, because they are no longer urged outwardly by the physical presence of the needle, collapse inwardly to cover the needle tip (FIG. 10B).

The '323 Rogers patent is relied on to disclose a check valve assembly. Rogers describes a catheter check valve assembly 10 which includes a body member 11, a separator 12, a separator body 13, a duckbill valve 14 and an end cap 15 in which is mounted a catheter 16. The separator body incorporates a finger tab 44, called a "head", for moving the separator from between an IV infusion position FIG. 3 (See also Col. 4:40-49) and a blood sampling position FIG. 4 (See also Col. 4:56-62). As described in the '323 patent specification, when the assembly 10 is in the blood sampling mode, a user "move[s] the separator 12 and separator body 13 to the

forward position shown in FIG. 4, thus opening duckbill valve 14 and permitting blood sample to be removed through the passageway 27."

To show that the device taught by Woehr and by Rogers are not compatible, will not work as a combination, and teach away from one another, FIG. 1 of Rogers and FIG. 10A of Woehr are reproduced below. Additionally, the needle guard taught by Woehr is transposed over the hub section 11 and the duckbill valve 14 taught by Rogers to highlight a nonsensical result produced by the combination.

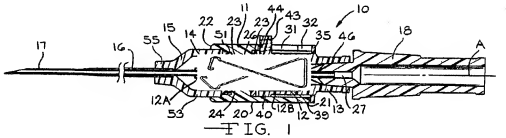


FIG. 1

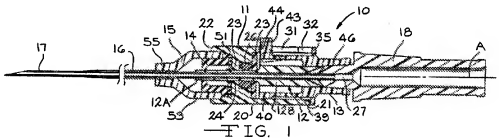
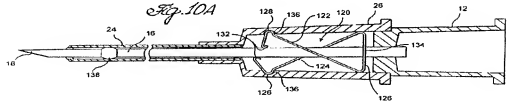


FIG. 1



In short, for the valve assembly 14 of the '323 Rogers patent to operate, the tubular portion 12A of the separator must project through both the annular seal 26 and the slit 48 (FIGs.

4 and 9) to provide a fluid pathway between the catheter tube 16 and the cavity at the luer lock fitting 46 (FIG. 3) of the body member 11.

Thus, to use the check valve assembly disclosed by the '323 Rogers patent with the catheter device disclosed by the '108 Woehr patent would require significant changes in the arrangement of various elements and would impact the functionality of the needle guard element if the changes proposed by the Examiner were made. For example, the hub of the Woehr catheter device would need to be modified to accept the valve assembly taught by Rogers while at the same time accommodates the guard at a proximal position thereof. Furthermore, a separator 12 and separator body would project over the needle and the needle guard disclosed by the Woehr reference would be positioned over the forward tubular portion 12A, the rearward tubular portion 12B, or both portions of the separator in the Examiner's proposed modification. However, doing so would first require widening or expanding the diameter of the opening of the proximal wall of the clip, which would make the opening larger than the crimp 138 on the needle and therefore will not engage the needle in the protective position. Also, neither Woehr nor Rogers show how these changes can be accomplished, which are not minor changes. Still furthermore, there is no indication whether even if the changes were made the combination would function or operate.

Still furthermore, because the clip disclosed by Woehr will be positioned over the tubular portion 12A disclosed by Rogers, the clip will never engage the needle as proposed by the Examiner. In other words, the tubular portion 12A disclosed by Rogers would act as a divider or wall and never allow the needle guard to engage the crimp on the needle to cover the needle tip. Accordingly, the proposed modification is defective and will not operate. Thus, the two references can not be combined to reject the claimed device without undue modification.

Still yet furthermore, independent claim 1 recites a catheter assembly wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub. In the overlay picture produced above, the guard disclosed by the '108 Woehr prior art reference would not be disposed between the catheter tube and the needle guard element in the catheter hub but instead positioned directly on top of the duck bill valve.

Somewhat similarly, claim 11 recites a catheter assembly in which the needle guard is positioned between the valve and the needle hub. Again, in the combination proposed by the Examiner, the guard disclosed by the '108 Woehr prior art reference would not be disposed between the valve and the needle hub of the '323 Rogers reference.

Claim 10 recites a different aspect of a catheter assembly in which a valve for regulating fluid flow is positioned inside the interior cavity of the catheter hub, and a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve. At the point where the two arms cross in the '108 Woehr reference, a gap or space between them are only sufficient to permit the needle 16 to extend therebetween. As suggested by the Examiner and in the overlay picture produced above, there would not be a sufficient gap to permit the tubular forward and rearward portions 12A, 12B to pass therethrough.

In view of the foregoing remarks, Applicant submits that the combination of Woehr and Rogers fails to teach or suggests all the limitations of the independent claims 1, 10 and 11 as required by MPEP 706.02(j). The remarks set forth by Applicant clearly rebuts the prima facie evidence proffered by the Examiner. Furthermore, it would be highly prejudicial to Applicant if the Examiner merely states that the present "remarks have been considered and are deemed not persuasive" in responding to present Request for Reconsideration.

Should the Examiner insist that the cited references disclose or suggest all the limitations and elements of the claimed catheter assemblies and that the two are combinable, Applicant respectfully requests that the Examiner provides specific references (by page, column, line number, or paragraph number) to such disclosure in compliance with MPEP § 2260 and 37 CFR §104(c)[1], which require a clear and complete Office Action. In addition, Applicant respectfully requests that such an Office Action, if necessary, be made non-final since the present Final Office Action is defective in this regard.

[1] (c) (2) In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified. (emphasis added).

Thus, rescission of the §103(a) rejection of the foregoing claims is respectfully requested. Since claims 2-9 depend from claim 1, they too are allowable for at least the same reasons and allowance is respectfully solicited.

§103(a) Rejection by Woehr et al. ('278) in view of Rogers et al. ('323)

As stated above, Applicant is unclear whether the '278 Woehr reference in combination with the '323 Rogers patent is relied on to reject the claims. The '278 Woehr patent is a continuation-in-part of the '108 Woehr patent, and thus contains similar disclosures with the addition of alternatives embodiments for the operating mechanism of the needle guard. However, as the same figures in the '278 Woehr reference are relied on, which are also relied on in the '108 parent patent, the combination is similarly defective.

In view of the foregoing remarks, the Application is thought to be in condition for allowance and early notice thereof is respectfully solicited.

Should the Examiner find it necessary to speak with Applicant's attorney; he is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,
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